

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF ARIZONA
3

4 **In Re: Bard IVC Filters**) MD-15-02641-PHX-DGC
Products Liability Litigation)
5) Phoenix, Arizona
6) **February 17, 2017**
_____)

7
8
9
10
11 **BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE**

12 **REPORTER'S TRANSCRIPT OF PROCEEDINGS**

13 **EIGHTH SCHEDULING CONFERENCE**

14 (Excluding Sealed Ex-Parte Discussion)
15
16
17
18
19
20

21 Official Court Reporter:
Patricia Lyons, RMR, CRR
22 Sandra Day O'Connor U.S. Courthouse, Ste. 312
401 West Washington Street, SPC 41
23 Phoenix, Arizona 85003-2150
(602) 322-7257
24

25 Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

A P P E A R A N C E S

Plaintiffs' Co-Lead/Liaison Counsel and State/Federal Liaison Counsel:

Lopez McHugh
By: **RAMON ROSSI LOPEZ**, ESQ.
100 Bayview Circle, Suite 5600
Newport Beach, CA 92660

Plaintiffs' Steering Committee Counsel:

Gallagher & Kennedy
By: **PAUL LINCOLN STOLLER**, ESQ.
By: **MARK S. O'CONNOR**, ESQ.
2575 East Camelback Road, Suite 1100
Phoenix, AZ 85016

Also for Plaintiffs:

Lieff Cabraser Heimann & Bernstein, LLP
By: **DANIEL E. SELTZ**, ESQ.
250 Hudson St., 8th Fl.
New York, NY 10013

Heaviside Reed Zaic
By: **JULIA REED ZAIC**, ESQ.
312 Broadway, Ste. 203
Laguna Beach, CA 92651

Goldenberg Law PLLC
By: **STUART GOLDBERG**, ESQ. (telephonic)
800 LaSalle Ave., Ste. 2150
Minneapolis, MN 55402

For Defendants:

Nelson Mullins Riley & Scarborough, LLC
By: **RICHARD B. NORTH, JR.**, ESQ.
201 17th Street NW, Suite 1700
Atlanta, GA 30363

Snell & Wilmer
By: **JAMES R. CONDO**, ESQ.
By: **AMANDA C. SHERIDAN**, ESQ.
400 East Van Buren
Phoenix, AZ 85004

P R O C E E D I N G S

THE COURTROOM DEPUTY: MDL 2015-2641, Bard IVC
Filters Products Liability litigation on for scheduling
conference.

Will the parties please announce.

MR. LOPEZ: Morning, Your Honor. Ramon Lopez,
Lopez McHugh, on behalf of the plaintiffs' Leadership Council.

THE COURT: Good morning.

MR. STOLLER: Morning, Your Honor. Paul Stoller,
Gallagher & Kennedy, on behalf of plaintiffs.

THE COURT: Good morning.

MS. REED ZAIC: Good morning, Your Honor.
Julia Reed Zaic on behalf of the plaintiffs.

MR. O'CONNOR: Morning, Your Honor. Mark O'Connor,
Gallagher & Kennedy, on behalf of the plaintiffs.

THE COURT: Good morning.

MR. NORTH: Good morning, Your Honor. Richard North
on behalf of the defendants.

MR. CONDO: Judge, good morning. Jim Condo,
Snell & Wilmer, on behalf of the defendants.

MS. SHERIDAN: Amanda Sheridan, Snell & Wilmer, on
behalf of defendants.

THE COURT: Okay. Good morning.

All right. And Mr. Goldenberg, I understand you are

10:02:34 1 on the phone and wish to speak as well this morning?

2 MR. GOLDENBERG: That is correct, Your Honor.

3 THE COURT: Okay.

4 I've been through the joint status report that you
10:02:44 5 provided to me, and I just want to take those issues one by
6 one and make sure I'm fully apprised of the parties'
7 positions.

8 The first issue you raised is defendants' desire to
9 file a motion for summary judgment on preemption.

10:03:00 10 MR. NORTH: Yes, Your Honor.

11 THE COURT: And, Mr. North or Mr. Condo, or whomever,
12 you indicate in your discussion that the basis upon which
13 you're going to argue these facts in this case differ from the
14 *Lohr* case, L-O-H-R, is that the statutory and regulatory
10:03:23 15 framework of the 510(k) review process has evolved
16 significantly since the time of *Lohr*, and that extensive
17 special controls that the FDA imposed in this case, as well as
18 clinical studies required by the agency, make this a different
19 case from *Lohr*.

10:03:47 20 My question is: How do you intend to present in your
21 summary judgment motion the evidence that the 510(k) process
22 is different and that this case had controls and tests that
23 distinguish it from *Lohr*?

24 MR. NORTH: Your Honor, primarily through a factual
10:04:07 25 showing of all of the evidence of what the FDA has required of

10:04:14 1 Bard over the years, the various correspondence, the various
2 rules. There's a special guidance document that the FDA has
3 developed for filters. There were certain requirements for
4 clinical studies which have evolved over the years. All
10:04:28 5 filters nationwide now are subject to a requirement by the FDA
6 for ongoing clinical studies. It's just a very lengthy
7 factual record that starts in about 2002 and is ongoing today,
8 that we believe will show the heavy involvement of the agency
9 to the level that it constitutes a requirement -- and I put
10:04:52 10 that in quotes because I believe that is the term in the
11 express preemption clause of the medical devices amendment
12 that the Supreme Court was interpreting in *Lohr*.

13 *Lohr*, by contrast, involved a device that was, even
14 though the decision was in the mid '90s, the device was
10:05:10 15 cleared in the early 1980s. There have been amendments to the
16 rules since that time. There have also been a lot of
17 pronouncements by the FDA since that time evolving on the
18 nature of their 510(k) review, and so there's a lengthy
19 factual record, both from the FDA's legal pronouncements or
10:05:36 20 agency pronouncements and from the factual issues with regard
21 to filters, and Bard's filters in particular.

22 THE COURT: Are those factual assertions that you're
23 going to be making disputed by the plaintiffs?

24 MR. NORTH: Well, I hate to predict what they're
10:05:58 25 going to say, Your Honor. I suspect --

10:05:59 1 THE COURT: But you have a pretty good idea.

2 MR. NORTH: I suspect what's going to be disputed
3 mostly is the legal implication of those facts. Do they
4 rise -- I mean, there's no disputing the fact there is a
10:06:11 5 guidance document with regard to filters. Everybody
6 recognizes that. There is no disputing the fact that the FDA
7 required us to conduct some clinical studies. They dispute on
8 what the significance of that is, and they claim that's
9 limited in scope.

10:06:26 10 But the facts of what the FDA has done are basically
11 fairly clear. I think the real point of dispute is going to
12 be what's the legal implication? Does that rise to the level
13 of a requirement under the Act, express preemption clause, and
14 does that distinguish this case, this device, from what was
10:06:47 15 addressed in *Lohr*.

16 THE COURT: Okay. Thanks. I understand that.

17 Defense counsel, why do you need an expert to address
18 those issues?

19 MS. REED ZAIC: Your Honor, the guidance documents
10:07:00 20 Mr. North referred to are not law.

21 THE COURT: I'm sorry?

22 MS. REED ZAIC: Are not law, Your Honor.

23 And the current state of the law is that 510(k)
24 devices, devices cleared via the 510(k) process, are not
10:07:13 25 preempted. They've cited no new law. Boiling it down to the

10:07:16 1 facts, they cite to the extensive special control the FDA
2 imposed. Those come directly from -- that quote comes
3 directly from the guidance documents they would like to put
4 forward, including reports from the FDA, which are subject to
10:07:28 5 interpretation. I'd like to hear what their experts have to
6 say about those guidance documents and those reports, as well
7 as their own experts.

8 We have no issue, obviously, with them bringing it
9 for a motion for summary judgment. We just feel it is
10:07:40 10 premature at this time.

11 THE COURT: Mr. North, are you going to rely on
12 experts at all in this presentation?

13 MR. NORTH: Your Honor, we are not, because we
14 believe the meaning of these various documents are for the
10:07:53 15 Court to determine. It's a legal conclusion as to what the
16 significance of these FDA pronouncements are.

17 We understand their contention that they need expert
18 testimony. We personally don't believe that is necessary, but
19 one thing we were talking about ourselves is we're not afraid
10:08:10 20 to put our cards on the table, we can go on and file this
21 motion if the Court permits it, and then give them two weeks
22 to look at it and tell us if they need time to do expert
23 rebuttal. And get an extension to respond, if necessary.

24 Our thought was to go in and get this in the hopper
10:08:27 25 because it's a very important issue, and I think it is a

10:08:30 1 developing issue under the law, and to put this in the hopper
2 as soon as we can, as opposed to waiting right at the end of
3 discovery before we're getting ready for trial.

4 But if they think they need an expert, why don't they
10:08:43 5 look at our motion, and then we can all convene in a telephone
6 conference and discuss what's necessary at that point.

7 MS. REED ZAIC: Your Honor, guidance documents are
8 not law. The quote from the FDA website with regard to the
9 definition of guidance is that the documents represent FDA's
10:08:59 10 current thinking on a topic. I can't cross-examine the FDA.
11 The guidance documents and reports from them are subject to
12 interpretation. I'd like to have our experts review that. If
13 they're not going to put up an expert, that's fine, but expert
14 interpretation is essential to looking at these guidance
10:09:13 15 documents. They're not law to be interpreted.

16 THE COURT: Give me a sense for what you think an
17 expert would say in response to the factual assertions that
18 Mr. North has described.

19 MS. REED ZAIC: Well, they've described facts --
10:09:25 20 their factual assertions include the extensive special
21 controls the FDA imposed on Bard's filters. That is a quote
22 from the guidance and the reports. I think an expert would
23 have to look at those facts and interpret to what extent were
24 they reviewed, and special controls put in place.

10:09:44 25 THE COURT: I'm not understanding what you're saying.

10:09:46 1 MS. REED ZAIC: Well, the -- they're claiming that
2 there were extensive controls put in place with regard to
3 these particular products. Extensive review comes down to
4 what kind of review did the FDA follow through with and
10:10:03 5 implement. We have FDA experts to interpret that.

6 THE COURT: And what argument would you make on the
7 basis of your experts' statements?

8 MS. REED ZAIC: I'm unsure what my experts would
9 actually say with regard to these guidance documents. That's
10:10:18 10 why I believe we need expert discovery with regard to this
11 issue.

12 THE COURT: If they're not planning to use an expert,
13 why doesn't Mr. North's proposal make sense to have them file
14 the motion, you can look at it. There's a tool in Rule 56,
10:10:33 15 56(d), if you think in fairness you need more discovery to
16 respond, which would be expert discovery, and that way we're
17 talking about something specific and not sort of making
18 assumptions.

19 In fact, it seems to me that would be better for you
10:10:48 20 because if you don't have the motion in hand and you're
21 working with your FDA experts, you don't have as clear a
22 picture of the target they're shooting at.

23 MS. REED ZAIC: Makes sense.

24 The reason why I'm sort of anticipating which
10:11:02 25 documents they're going to use is that two Mondays ago, we

10:11:06 1 were arguing dispositive motions in Florida on G2. So I have
2 a sense of the documents they would use.

3 If the Court is inclined to allow that to go forward,
4 again, we're not here to say there's no motion to be brought.
10:11:15 5 It's just we feel it is premature at this time considering how
6 far we are into the process. We didn't just start fact
7 discovery, we're headed into expert discovery now with reports
8 due in a matter of weeks.

9 THE COURT: When are you thinking you would file this
10:11:32 10 motion, Mr. North?

11 MR. NORTH: Your Honor, we are aiming for
12 approximately a month. By the end -- by March 17. It's a
13 Friday.

14 THE COURT: So it would be after the disclosure --
10:11:41 15 the initial disclosure of plaintiffs' experts, so it doesn't
16 sound like it would interfere with your ability to get that
17 work done.

18 Is that correct?

19 MS. REED ZAIC: I apologize. I was verifying the
10:11:53 20 deadline that our reports are due --

21 THE COURT: March 3rd they're due. And if he's going
22 to file it two weeks later, then working on this motion and
23 your experts wouldn't --

24 Well, but I suppose, Mr. North, you will be taking
10:12:05 25 the position that whatever they can use in response to your

10:12:10 1 motion is limited to what they disclosed on March 3rd; right?

2 MR. NORTH: If there is something additional,
3 specific to that motion. I mean, this motion is important to
4 us. I don't think I would object to that necessarily. I'm
10:12:33 5 having a hard time fathoming what that could be, because we
6 have seen their regulatory expert's opinions in another case,
7 and it is close to 300 pages long. He certainly has looked at
8 virtually everything we're going to be submitting anyway. So
9 I find it difficult to believe there's going to be anything
10:12:48 10 that is not covered already. But if there is something
11 specific, if they want to add on that one specific thing, I'm
12 not going to stand in the way of that.

13 MR. LOPEZ: Your Honor, if I may --

14 THE COURT: Pull the mic over, would you, please.

10:13:04 15 MR. LOPEZ: We're talking about -- may I just step up
16 here?

17 THE COURT: Sure.

18 MR. LOPEZ: We're talking about a guidance document
19 that is, I think, dated 2015. The devices involved in this
10:13:17 20 case went through 510(k) processes between 2002 and 2013.

21 Our experts -- though they haven't looked at that
22 guidance document, our experts, when we talked to them about
23 it, agree that the guidance document, doesn't matter when, the
24 guidance document is not law, it's a suggestion by FDA as to
10:13:40 25 better practices that a company can or cannot follow. They

10:13:45 1 don't have to follow. In fact, they're encouraged that that
2 is a minimum standard.

3 So if this -- I mean, I think this is the mini trial
4 if you read the *Sisson* case, Your Honor, I know it is
10:13:57 5 premature maybe to talk about that in the *Husky* case, the
6 Fourth Circuit case on why the 510(k) --

7 THE COURT: I have not -- I have not read them
8 recently.

9 MR. LOPEZ: Those are the only two appellate court
10:14:08 10 cases that exist where the Fourth Circuit -- and this is
11 recent, in fact it involves Bard in the TBN litigation, where
12 both of those courts, citing *Lohr* and other cases, have said
13 the 510(k) process itself is not relevant. It's not what FDA
14 did or didn't do. That process is not admissible in a medical
10:14:31 15 device case.

16 And now we want to go from that to whether or not a
17 single document that did not exist in any time when these
18 devices were cleared for marketing now becomes a preemption
19 case. Now, that's point one.

10:14:45 20 Point two --

21 THE COURT: Point one, you're arguing the merits,
22 Mr. Lopez.

23 MR. LOPEZ: Sorry?

24 THE COURT: You're arguing the merits in that point
10:14:52 25 one, and I'm not here to try to figure out who is right on the

10:14:55 1 merits; I'm trying to figure out the most efficient way to tee
2 up a motion that the defendants have a right to bring.

3 MR. LOPEZ: I understand. And I didn't mean to do --
4 I did that for a purpose. I was leading up to why --

10:15:06 5 THE COURT: Okay --

6 MR. LOPEZ: -- this process is not just -- they file
7 a motion, we go to our experts, and our experts file some kind
8 of counter-report or declaration.

9 This is an intensive factual issue. In other words,
10 Mr. North just said, we are going to pile up documents of what
11 happened at FDA, and that's going to be the factual record.

12 And what I want to bring to the Court's attention, we
13 don't have a factual record of what happened at FDA. They
14 only have their version of what happened. We cannot -- under
15 the regulations, we can't do discovery on FDA. So -- and it
16 could be that if we're going to go the distance with this
17 issue, that we're going to have to ask the Court to contact
18 someone at FDA to see if they'll waive their right to
19 basically ignore subpoenas for us to take depositions.

10:15:56 20 If we're going to do that for 12 years of 510(k)s and
21 about 11 of 510(k)s in this case, we might have to take 20 FDA
22 official depositions -- officials' depositions.

23 So did the -- the factual record is what we have with
24 Bard, and the other part is we don't have. We will have to
10:16:15 25 develop that factual record to see whether or not, in fact,

10:16:20 1 all of the things that Mr. North is going to allege through
2 their facts in fact happened at FDA.

3 So I just want to bring that to the Court's
4 attention. This is going to be an intensive process if we go
10:16:31 5 down this road. We're going to want due process. We're going
6 to want a fair hearing. And the only way for us to get a fair
7 hearing is to find out what really happened at FDA, and we
8 have not been able to do that because of the statute that says
9 we can't.

10:16:44 10 THE COURT: I hear what you're saying, but I'm not
11 understanding what you're proposing.

12 Wouldn't it make sense for to us have this discussion
13 after Bard's motion is on the table and we can see what
14 they're arguing and what they're using to support it, and then
10:16:58 15 we can talk about do we need experts, do we need -- I don't
16 want to suggest I'm inclined to do it, but do we need some
17 additional discovery.

18 Right now, you may know what's going to be in it, but
19 I don't have any sense without looking it over. So I guess
10:17:14 20 I'm not understanding why we shouldn't get them to file it,
21 and then have an informed decision about what you need to do
22 to fairly respond to it.

23 MR. LOPEZ: I understand the practicality of that,
24 Your Honor. I just wanted to forewarn the Court that whenever
10:17:27 25 that happens, it is going to be fairly intensive -- it's going

10:17:30 1 to be another section of this MDL, that additional discovery
2 that's going to have to happen.

3 But I understand what you're saying. You don't want
4 to know about that right now. You want to know about it after
10:17:40 5 they file their motion and we file our opposition to it to
6 bring to the Court's attention the enormity and extensiveness
7 of what we need to do to counter it. I get it.

8 THE COURT: I understand that. I don't want you to
9 leave today thinking I'm in agreement with the notion we're
10:17:57 10 going to do extensive FDA discovery. That's clearly an
11 undecided issue.

12 MR. LOPEZ: We don't want to do it.

13 THE COURT: Right. But this issue is one that's
14 coming. You know it's coming in the case.

10:18:07 15 MR. LOPEZ: Correct.

16 THE COURT: There's going to be a preemption
17 argument. That's been apparent from the day you filed it, I'm
18 sure, and we just need to figure out the most efficient way to
19 deal with it.

10:18:16 20 MR. LOPEZ: I hear Your Honor. Thank you.

21 THE COURT: Anything else from the plaintiffs' side?

22 MS. REED ZAIC: I wanted to clarify the exchange
23 there. My understanding is that they will file a brief, and
24 then we'll have a conversation --

10:18:26 25 THE COURT: Well, we're going to actually set some

10:18:27 1 dates for that, yeah.

2 MS. REED ZAIC: Okay. But I think Mr. Lopez said
3 we'll be filing an opposition --

4 THE COURT: No. Not until we talk.

10:18:35 5 MS. REED ZAIC: Okay. Wanted to clarify.

6 THE COURT: You think a month, March 17th? Does that
7 work for you, Mr. North?

8 MR. NORTH: Yes, Your Honor.

9 THE COURT: Okay. We'll call this the preemption
10:18:50 10 motion for summary judgment to be filed by March 17th.

11 I haven't looked at the order. When's our next
12 status conference?

13 MR. NORTH: We don't have one, Judge.

14 MS. REED ZAIC: We don't have one.

10:19:06 15 THE COURT: Okay. We'll be setting one. But I'm
16 guessing it will be farther out than the end of March.

17 MR. LOPEZ: Your Honor --

18 THE COURT: Yeah?

19 MR. LOPEZ: -- just I'll bring the Court's attention,
10:19:18 20 we're starting our first bellwether trial, and it's a state
21 court case, not a federal court case, on March 20th, and I'm
22 sure Mr. North and others, I know virtually everybody at this
23 table is going to be involved in that trial from about
24 March 20th to probably April 10th. So if we can set -- if we
10:19:38 25 can take that into consideration as we schedule things and as

10:19:41 1 we schedule the next CMC, that would be terrific.

2 THE COURT: All right. I've been looking at the
3 calendar. I'd like to hold another status conference on
4 Wednesday, May 3rd. That's really about the only available
10:23:21 5 date in late April or early May.

6 I'm scheduled to be in trial. I don't know for sure
7 if the case is going to go, but if it does, we'll probably
8 have to do it at about 4 o'clock and just push through it. So
9 let's set it for -- let's set it for 3:00 p.m., but you may
10:23:39 10 get a notice we're moving it to 4:30, probably, if the case is
11 actually going to go to trial.

12 And I think since you're going to be in trial in the
13 state case, what would make sense would be after you're done
14 with that trial to look over the motion, to confer, to file
10:23:58 15 before this May 3rd status conference a joint report. And if
16 the plaintiffs are of the view that you need expert testimony
17 or other factual information to respond, then lay it out in
18 that report, and we can talk about that on May 3rd and decide
19 if I'm just going to require a response or, if not, what
10:24:19 20 exactly needs to be done to get a response filed.

21 Any questions about that?

22 MR. NORTH: Nothing, Your Honor.

23 MR. LOPEZ: No, Your Honor.

24 MS. REED ZAIC: No, Your Honor.

10:24:32 25 THE COURT: Okay.

10:24:43 1 The next topic is the plaintiffs' request to defer
2 expert disclosures on the Meridian and Denali devices. As you
3 all know, we've already extended the expert disclosure
4 deadline from December 6th to March 3rd. And when I did that,
10:25:00 5 I said in the order that I was not inclined to grant
6 additional extensions.

7 I understood from what the plaintiffs said in the
8 joint report the points about how Meridian and Denali are not
9 in the bellwether group, they could be -- the disclosures
10:25:16 10 related to those products could be deferred without
11 interfering with our bellwether process.

12 What I couldn't understand, however, is why you need
13 to defer them. Why you don't think you can meet the March 3rd
14 date. There was a reference to unresolved privilege issues,
10:25:32 15 but I didn't see what the reason was that you don't think you
16 can produce those experts by March 3rd.

17 MR. LOPEZ: Thank you.

18 Let me give you just a little bit of background. One
19 thing we didn't add is that the early remands, the ten early
10:25:50 20 remands that we've talked about, also none of those are
21 Meridian or Denali. I think the docket will reflect that I
22 would guess the majority, if not all of the early-filed cases,
23 are either Recovery, G2, or Eclipse.

24 THE COURT: On that point, Mr. Lopez, do you agree
10:26:08 25 with the defendants' assertion that between Meridian and

10:26:11 1 Denali, it accounts for about 25 percent of the cases in the
2 MDL?

3 MR. LOPEZ: Yeah. I have no reason to dispute that.
4 I'm sure if that's the data, that they would accurately report
10:26:21 5 that to the Court. I haven't verified it, but I'm not going
6 to dispute it.

7 So what we have, Your Honor, just to refresh your
8 recollection a little bit about this process, is that we had
9 this 4.6 million pages of documents that all of a sudden
10:26:39 10 got -- we got produced upon us between September 15 and
11 December 1, and we did a really good job of getting those
12 documents reviewed. We haven't reviewed them all, there's
13 some metadata there that still has not been looked at. We
14 took depositions. We have depositions that involve these
10:27:06 15 products that just finished whenever the discovery cutoff was,
16 February 3rd. So we're talking two weeks ago.

17 The record -- and then, of course, we have these 3300
18 redacted documents, as well as I think it was 28,000 documents
19 that are now in a privilege log, and for the most part these
10:27:32 20 deal with Denali and Meridian time periods.

21 So I guess the issue -- the real issue is for the
22 next year, Meridian and Denali, for purposes of any trials,
23 whether it be bellwether trials, early remands, or even the
24 state court cases that are currently filed that will have
10:27:54 25 trial dates are not going to involve these two devices.

10:27:56 1 Now, I'll just tell you that we -- our main expert,
2 Dr. David Kessler, our regulatory expert, former commissioner
3 of FDA, is now being given about two weeks because he's
4 been -- we just haven't been -- he's been working on another
10:28:10 5 case to put together what took him four months to put together
6 for a Recovery and G2, he's got two weeks now to figure out
7 what he's going to say about the Denali and the Meridian. He
8 can do that.

9 I mean, don't get me wrong, I think we -- we have
10:28:26 10 evidence that will show breaches and liability as to those two
11 devices. But I think the idea that we can have a thorough
12 complete report with the fact that this discovery only ended
13 at the end of -- at the beginning of February, only because we
14 got these documents so late, is just something I don't think
10:28:50 15 we can do.

16 Now, my thought was maybe allow at least that portion
17 of our experts' reports, meaning the Denali and the Meridian,
18 to at least give us an extra month, or at least allow us to
19 resolve some of these redaction and privilege log issues if we
10:29:13 20 can. At least leave open the idea that, at no fault of ours,
21 we've received a lot of the evidence as it respects those two
22 devices very late, evidence we probably should have gotten
23 much sooner.

24 You know, it took us about five years to develop the
10:29:34 25 case, going back to some of the early depo- -- the reason we

10:29:37 1 were able to take so many depositions in this case in a
2 relatively short period of time, because, as Your Honor knows,
3 we took a lot of depositions before this MDL, and we haven't
4 repeated those depositions. But that was another two-year
10:29:49 5 process.

6 So now we're -- we basically have two weeks, two or
7 three weeks to put together expert testimony or expert reports
8 on two devices that probably will not see a trial date until
9 2018.

10:30:08 10 And so that's essentially it, Judge. I mean, look --
11 could we have something in these reports by March 3rd that
12 will give the defendants at least notice of plaintiffs'
13 position as to why the Denali and the Meridian are defective
14 and why they didn't warn appropriately, or why they failed to
10:30:28 15 meet the substantial equivalence of the predicate device? We
16 can do that, and there will be some evidence in there, but it
17 will not be a fully developed report because our experts
18 simply don't have time to either go through the evidence that
19 exists now -- I don't know how many depositions, I think we
10:30:45 20 took 12 or 13 depositions in January. We're still getting
21 final drafts of those now.

22 So maybe there's an in-between position here,
23 Your Honor, where we can maybe have the right to supplement
24 these as some of these additional things develop with respect
10:31:02 25 to privilege log and redaction documents that still are not

10:31:05 1 resolved, and that these experts be given an opportunity to
2 supplement their reports at some time beyond March 3rd.

3 There's no reason to depose them on those right now
4 because there are no trials this year in either state or
10:31:21 5 federal or any of the bellwether cases, or in any of the early
6 remands that involve either one of those two devices.

7 So that's our position on that, Your Honor. I just
8 think we're at a point where we can provide something, but
9 there's no way our experts can provide a thorough report based
10:31:38 10 on the current state of the evidence in the time they have.

11 THE COURT: You mentioned one expert, and then after
12 that you used the phrase "experts." Are you going to have
13 more than one expert on defects in Meridian and Denali?

14 MR. LOPEZ: We are.

10:31:51 15 THE COURT: How many?

16 MR. LOPEZ: Well, we have two regulatory experts and
17 we have -- I'm counting as I'm thinking about it.

18 THE COURT: That's fine. Really, my question is a
19 bit different. Will the experts on Meridian and Denali be the
10:32:11 20 same people who are doing the reports on the earlier versions
21 of the filters?

22 MR. LOPEZ: Oh, yes. Yes. Yes.

23 THE COURT: Okay. One of my concerns is I think an
24 important point in this case will be *Daubert* motions. It
10:32:25 25 seems to me that's one of the principle issues that an MDL can

10:32:29 1 help resolve. And you mentioned a moment ago we don't need to
2 depose these folks until next year. Well, that might be true
3 for a bellwether trial, but it seems to me one thing we
4 absolutely should do is have all experts on the table when we
10:32:44 5 get to *Daubert* motions so that I can rule and not have a
6 situation where I'm ruling in part and we're having to come
7 back to it later with respect to other filters.

8 So I am going to want everybody deposed, all the
9 reports on the table before we get to that point in time.

10:32:59 10 But I do understand what you've said about the
11 situation. I want to hear from defense counsel. Did you have
12 other points you wanted to make?

13 MR. LOPEZ: No, that it was, Your Honor. Thank you.

14 THE COURT: Okay.

10:33:14 15 MR. NORTH: Thank you, Your Honor.

16 If it would be of any help, and maybe just of
17 interest, if I could approach, Traci.

18 I've got copy of this for the plaintiffs.

19 Your Honor, this is a breakdown of the filter cases
10:33:37 20 in the MDL by filter type, according to our database, as of
21 February 7, 2017. And that's where we drew the numbers we had
22 in our submission.

23 Your Honor, with all due respect to the plaintiffs,
24 we suggest that this request comes too late. We are literally
10:33:56 25 two or three weeks away from expert disclosures. And they are

10:34:01 1 raising this for the first time.

2 It is an issue they could have raised much earlier.
3 They could have raised this in December at the status
4 conference. They could have raised this even earlier when
10:34:12 5 they asked for an extension of fact discovery. They never
6 raised it.

7 We are very concerned about this because what we
8 think it in effect does is bifurcates this proceeding into two
9 MDL's. And if they were to get their request to indefinitely
10:34:30 10 delay these depositions or these disclosures, what we would
11 have is one MDL proceeding with the early generation filters,
12 which I believe are the filters they want to try. And then
13 they would create an entirely second MDL that, under their
14 scenario, wouldn't even really get geared up until next year
10:34:51 15 at the earliest on the later generation filters, which I will
16 say conversely are filters we would like to try.

17 And I think what this does is create two separate
18 proceedings, and they're asking for this at the eleventh hour
19 with only three weeks to go.

10:35:05 20 Now, they raised the privilege log, for example,
21 Your Honor. I spoke with Ms. Helm in my office this morning,
22 who spearheads privilege issues for us, and she's been working
23 with Mr. Combs from the Gallagher & Kennedy firm on these
24 issues. Mr. Combs had some questions about the privilege log.
10:35:25 25 She provided some additional information, and there's no issue

10:35:28 1 on the table right now. He's supposed to get back to us if
2 there are questions.

3 These are things that, if they really believe this
4 was essential before they could do their experts, they needed
10:35:39 5 to have pushed this faster and harder. Because there is no
6 issue on the table. They've mentioned this redaction issue,
7 and we've provided them with a log of that, as required by the
8 ESI protocol. But the ESI protocol says we are entitled,
9 particularly when we started doing this no-eyes review, we're
10:35:59 10 entitled to redact nonresponsive portions of documents that
11 had commercial or propriety information about other products.
12 And my understanding is now they have a log about this.

13 I don't believe these are justifications. And we're
14 working out any further questions they may have and stand
10:36:16 15 ready to do so, and to do so on an expedited basis. But I
16 don't believe these are justifications for prolonging what
17 everybody had expected to be expert disclosures coming up on
18 March 3rd.

19 And what I'm concerned about also is even if we were
10:36:32 20 to extend this 30 or 60 days, we're still duplicating efforts
21 here. It's going to require two different reports from these
22 experts, the same experts. It's going to require two
23 different depositions from the same experts. It even may
24 require two different *Daubert* hearings, as the Court
10:36:52 25 questioned, of these experts.

10:36:53 1 And we believe this is very inefficient. If -- and
2 we propose this as a protection for them. If they were to
3 find something in their discussions on the privilege log, or
4 if they were to find something regarding a redacted document
10:37:11 5 that somehow later gets produced after agreement, that they
6 believe impacts an expert's opinion, necessitating a very
7 limited and targeted supplement in the next month or six
8 weeks, we're not going to stand in the way of that.

9 But absent that, we believe that we should proceed as
10:37:31 10 planned and as envisioned for over the last year to have
11 expert disclosures as to all filters at the same time, as
12 planned.

13 THE COURT: Do you disagree at all, Mr. North, with
14 the assertion that there were 4.6 million documents produced
10:37:51 15 between September and December?

16 MR. NORTH: The numbers I've been given are less than
17 that. Probably three to three and a half million, but I don't
18 have the exact count, to be candid, Your Honor.

19 THE COURT: Okay.

10:38:14 20 MR. NORTH: Oh. If I could add one more thing,
21 Your Honor. It's not like this was the first time documents
22 concerning these filters had ever been produced. In the past
23 litigation, Meridian and Denali had been key words that had
24 been used in a lot of the ESI that Mr. Lopez's firm had asked
10:38:33 25 for.

10:38:34 1 THE COURT: Okay.

2 All right. I absolutely do not want this to become
3 two MDL's. I don't want an expert deposed twice. And we
4 don't want two rounds of *Daubert* motions.

10:39:10 5 I do think you all have been working hard, you've
6 covered a lot of ground, and I think you're all to be
7 commended for having done that. There's a lot to absorb. So
8 I'm going to extend somewhat the experts, but they're going to
9 be within the overall expert schedule.

10:39:25 10 So with respect to Meridian and Denali, the
11 plaintiffs' report will be due on April 7th, which is a month
12 and three days extension.

13 Defendants will have the same amount of time to
14 respond, so May 12th will be the deadline for the defendants'
10:39:41 15 response.

16 June 9th for the plaintiffs' rebuttal.

17 And that still leaves more than a month before the
18 July 14th expert deposition cutoff date to depose these
19 experts once. So make sure that these experts are scheduled
10:40:00 20 in -- well, between June 9th and July 14th. That way we still
21 finish all of the expert depositions at once, we're teed up
22 for *Daubert*, we're not dividing the case into two MDL's, but
23 it gives plaintiffs a little breathing room on Meridian and
24 Denali.

10:40:18 25 All right. The next issue is the deposition of

10:40:22 1 Mr. Randall. I've read what you've submitted -- well, I've
2 read what you submitted in the joint report, and I read
3 portions of the deposition excerpts you have submitted. I
4 didn't read all 40 pages the plaintiffs asked me to or all
10:40:37 5 of -- well, I think I might have read all the defendants'
6 because it was much shorter.

7 Is there anything that wasn't said in the joint
8 report that you want to say on this issue?

9 MR. STOLLER: No, Your Honor, I don't think so.

10:40:55 10 MR. NORTH: Nothing, Your Honor.

11 THE COURT: Okay.

12 As I read that deposition, I did not believe
13 Mr. Randall was being evasive. I didn't believe he was trying
14 to prolong the deposition. He was being careful. But I
10:41:09 15 didn't think there was anything improper. I think seven hours
16 is enough for him. I think when it's added to the seven hours
17 that's happened on the 30(b)(6) for a total of 14 this man's
18 been in the witness chair, that's enough, so I'm not going to
19 grant an additional period of time for the Randall deposition.

10:41:31 20 The next issue is the production of documents related
21 to these employees who may have been disciplined or fired for
22 off-label promotion.

23 My question to -- were you going to say something?

24 MR. STOLLER: I was going to say, Your Honor, this is
10:41:45 25 the issue that Mr. Goldenberg is handling.

10:41:49 1 THE COURT: Okay. That's fine.

2 My question to plaintiffs' counsel is: What's wrong
3 with defendants' proposal, which is on page 16 of the joint
4 report, to produce the portions of the employment files that
10:42:03 5 relate to this issue? As opposed to turning over the entire
6 employee files for these six individuals.

7 MR. GOLDENBERG: Well, thank you, Your Honor. This
8 is -- obviously --

9 Can everybody hear me okay?

10:42:17 10 THE COURT: Yes, we can.

11 MR. GOLDENBERG: This is the first time we actually
12 were given this proposal, and certainly we would accept that.
13 The problem with it is, is that there's more information that
14 would be relevant that is part of this request.

10:42:33 15 Each of these employees signed elaborate separation
16 agreements that related to how they were terminated or let go.
17 And none of them could, quote, remember what was in those
18 agreements when we took their depositions. None of them had
19 these documents, and these are all part and parcel, like what
10:42:54 20 we're requesting here, because it is -- it is almost a clean
21 sweep of all of these people when 2008 comes along, Jason
22 Greer is fired for off-label promotion, and this scheme is
23 finally put aside by the new -- apparently by the new
24 president.

10:43:17 25 So this is why we're requesting that information, and

10:43:20 1 it's incredibly important and relevant to what we're proving
2 in the off-label promotion.

3 THE COURT: Well, let me ask you a question. What
4 the defendants proposed to produce were essentially what I had
10:43:40 5 required on the FDA warning letter, so it would be, for
6 example, I'm now reading on line 15 of page 16, documents from
7 the files relating to any internal discipline, reprimands,
8 adverse consequences, negative employment reviews or
9 comparable information taken against any of these individuals
10:44:05 10 on the basis of off-label promotion of Bard's filters.

11 What's missing from that description?

12 MR. GOLDENBERG: Okay. Here's -- here's what I'm
13 concerned about. When they're saying off- -- they're not
14 really saying off- -- I guess I'm looking at this last line
10:44:24 15 here.

16 THE COURT: Look at line 21, and they're proposing to
17 do this for off-label promotion of Bard IVC filters.

18 MR. GOLDENBERG: Okay. The concern is whether or not
19 that includes this -- these elaborate separation agreements
10:44:40 20 that are related to that.

21 THE COURT: Well, my view is that if there's anything
22 in those separation agreements that refers to internal
23 discipline, reprimands, adverse consequences, negative
24 employment reviews or comparable information about off-label
10:44:56 25 promotion, they have to produce it.

10:45:01 1 MR. GOLDENBERG: Okay.

2 THE COURT: With that understanding, are you
3 comfortable with that?

4 MR. GOLDENBERG: I am, Your Honor.

10:45:07 5 THE COURT: Okay.

6 Any comments, Mr. North?

7 MR. NORTH: No. That's fine, Your Honor.

8 THE COURT: So I will reflect that in the order that
9 comes out after today.

10:45:20 10 You had a Section 6 titled Other Issues Not Yet Ripe
11 for the Court, and it listed five that you're discussing.
12 Defendants note that these were raised on February 8th.

13 My question is: What is your best estimate on timing
14 as to when you're either going to have them resolved or be at
10:45:42 15 an impasse? Because what I don't want to do, and I know you
16 don't either, is have this resurface in three months. We need
17 to deal with it while it's on the table.

18 MR. NORTH: Your Honor, if I may, I know, for
19 example, that we have set up a second meet and confer phone
10:45:57 20 call on the last two items on that list for Wednesday with the
21 team of the plaintiffs' attorneys that are handling that.
22 They were unaware of some things that had happened in
23 discovery since they served those requests back in October,
24 and we've pointed them to where a lot of that information has
10:46:12 25 been divulged. So I'm confident we ought to be able to work

10:46:17 1 that out next week, I would hope. If for some reason they
2 think there's still an impasse, they can come to the Court on
3 that point.

4 On the first point with regard to the placeholders
10:46:28 5 that Mr. Stoller has mentioned, we are working on that.
6 That's required us to go consult with both of our vendors. We
7 hope to be able to have a meaningful dialogue with Mr. Stoller
8 early next week. And I think we're going to be able to
9 satisfy him, but if we don't, I think the impasse will be next
10:46:46 10 week.

11 And as far as privilege issues are concerned, if
12 there is an issue, they need to tell us about it, because
13 right now we're waiting to hear back from them since we gave
14 them the additional information they requested.

10:46:58 15 THE COURT: Well, what if we were to say that by
16 March 10th the parties will present a matrix to me of any
17 outstanding issues. Outstanding discovery issues. That will
18 give you about three weeks to work through things, get
19 hopefully everything resolved, but anything that can't be
10:47:12 20 resolved, you know how to do one of those matrices that I've
21 been requesting, and you can submit it by that date so I can
22 rule.

23 MR. NORTH: I think that's fine, Your Honor.

24 MR. LOPEZ: That works, Your Honor.

10:47:23 25 THE COURT: Okay. That's what we'll do with Item 6,

10:47:26 1 then.

2 Do plaintiffs have any objection to the
3 recommendation in part 7 from defendants that for future joint
4 reports, drafts get exchanged four business days before the
10:47:44 5 deadline with responses two business days?

6 MR. LOPEZ: Well, I mean, as a hard and fast rule,
7 I'd say yes, only because this is -- we're real-time every day
8 something -- I think we -- so far it's been okay. We get --
9 we usually get our stuff to them by the Wednesday before the
10:48:01 10 Monday. And I know it's hard. I mean, they're three hours --
11 you know, they're in Atlanta and we have that time zone. But
12 we usually bring -- there's a lot of things happening, Judge,
13 so because our CMC's are sometimes two months apart, I mean --
14 I would say we will start the process there, but just leave
10:48:19 15 open the idea that it could be even 24 hours before an issue
16 comes up that might be something that we'd like the Court to
17 deal with at the hearing. But I think as far as imposing at
18 least starting that process four business days before,
19 certainly, we're more than willing to do that.

10:48:37 20 THE COURT: Well, what I will do is I'm going to
21 adopt this in my order, and I will say there will be an
22 exception for exceptional circumstances. But it does seem to
23 me that it's likely that every issue you could identify the
24 day before, you could identify four days before. But we'll
10:48:51 25 have an escape clause if there's something that really does

10:48:54 1 pop up in the last couple of days.

2 MR. LOPEZ: Thank you, Your Honor.

3 THE COURT: All right.

4 Mr. Lopez had contacted our office and indicated
10:49:09 5 plaintiffs' counsel would like to confer with me ex parte
6 about plaintiffs' side budgeting and auditing and accounting
7 stuff, so I'm happy to do that. We'll do it on the record.
8 But it's consistent, I assume, with the reports you've been
9 submitting that I've reviewed. So we'll have to do that
10:49:27 10 before we break.

11 Are there other matters the plaintiffs want to raise?

12 MR. LOPEZ: No, Your Honor.

13 THE COURT: How about from defendants?

14 MR. NORTH: Nothing further, Your Honor.

10:49:36 15 THE COURT: Okay. So May 3rd at 3:00 p.m. will be
16 our next status conference. I'll reflect these other rulings
17 in the order that comes out.

18 And we can excuse the defense counsel, and we'll go
19 ahead and address those plaintiff budgeting issues. If we
10:49:54 20 have defense counsel on the phone, they should hang up at this
21 point.

22 And thank you all for being here.

23 MR. NORTH: Thank you, Your Honor.

24 MR. LOPEZ: Thank you, Judge.

10:50:02 25 (The sealed ex-parte discussion between The Court and

10:50:02 1 plaintiffs was reported but not transcribed herein.)

2 (End of partial transcript.)

3 * * * * *

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 28th day of February, 2017.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter